Remarks/Arguments:

Introduction

Claims 1-26 are pending. Claims 1, 5, 8, 11, 17 and 20 have been amended. Claims 1, 8 and 17 have been amended to further describe the graft material as being non-textile. Support for these amendments may be found in originally filed claims 5, 11 and 20, which have also been amended accordingly. Claim 8 has been amended to further describe the substantially planar graft and stent material comprising planar graft material and planar stent material.

Section 112 Rejections

Claims 5, 11 and 20 are rejected under 35 U.S.C. §112, second paragraph. The Examiner alleges that the term "non-textile" in is conflict with the term "non-woven" contained in the corresponding independent claims. The Examiner asserts that a "non-woven" material is a "textile" material. Applicant respectfully traverses.

One of ordinary skill in the art would readily understand that the term "non-woven" can include certain textile materials, such as knitted fabrics, braided fabrics and the like. One of ordinary skill in the art would also readily understand that the term "non-textile" excludes the use of textile materials, such as woven fabrics, knitted fabrics, braided fabrics and the like, while including other materials, such as extruded sheets. Accordingly, the term non-woven precludes the use of woven materials, while including the possible use of other textile materials. Thus, the term non-textile in originally filed claims 5, 11 and 20 further limited the scope of the non-woven graft strips of the corresponding independent claims. Nevertheless, to advance prosecution on the merits, the term "non-textile" has been added to independent claims 1, 8, and 17 and has been deleted from claims 5, 11 and 20.

Reconsideration and withdrawal of the rejections under Section 112 are respectfully requested.

Summary of the Present Invention

The invention as presently defined by independent Claim 1 is directed to a method of making a tubular stent/graft assembly. The inventive method of Claim 1 comprises the steps of (i) forming a substantially planar strip and wire assembly comprising non-textile planar graft material formable into a graft and planar stent wire formable into a radially adjustable stent, wherein said wire is attached lengthwise along the length of said planar strip; and (ii) helically winding said substantially planar strip and wire assembly to form said tubular stent/graft assembly. (emphasis added)

The invention as presently defined by independent Claim 8 is directed to a method of making a stent/graft assembly. The inventive method of Claim 8 comprises the steps of forming a substantially planar graft and stent material assembly comprising non-textile planar graft material and planar stent material; and winding said substantially planar graft and stent assembly to form said stent/graft assembly. (emphasis added)

The invention as presently defined by independent Claim 17 is directed to a method of making a tubular stent/graft assembly. The inventive method of Claim 17 comprises the steps of (i) forming a substantially planar strip and stent assembly comprising planar non-textile graft material formable into a graft and a planar stent formable into a radially adjustable stent, wherein said planar stent is attached along the length of said planar strip; and (ii) helically winding said substantially planar strip and stent assembly to form said tubular stent/graft assembly. (emphasis added)

As used in the present application, the term "planar" specifically refers to a structure that can be "substantially defined in two dimensions". (Specification, paragraph [0058]). In other words, a planar structure is essentially flat, where it can be defined by vectors in two dimensions, and having only a minimal, if any, third dimension (*Id.*), which precludes structures having significant third dimensions, for example traversingly overlapping or overlaying members.

Thus, the planar stent wire of claim 1, the planar stent material of claim 8, and the planar stent of claim 17 all refer to an essentially flat stent arrangement formable into the planar stent-graft assembly. As discussed below, such a claimed planar stent structure does not include stent structures having overlapping or overlaying stent wires, such as braided stents, because the overlapping portion is not an essentially flat arrangement which can be defined as having only two dimensions because it has a third dimension at the point of overlapping.

Section 103 Rejections

Claims 1-9, 11-24 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,824,040 to Cox et al. (hereinafter "Cox") in view of either one of U.S. Patent Nos. 5,928,278 to Shannon et al. (hereinafter "Shannon") or U.S. Patent No. 6,517,571 to Brauker et al. (hereinafter "Brauker") and any of U.S. Patent Nos. 5,755,774 to Pinchuk (hereinafter "Pinchuk"), 5,800,520 to Fogarty et al. (hereinafter "Fogarty") or 5,732,004 to Dereume et al. (hereinafter "Dereume"). Applicant respectfully traverses. Claims 10 and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cox in view of either Shannon or Brauker and any of Pinchuk, Fogarty or Dereume in further view of U.S. Patent No. 6,361,637 to Martin et al. (hereinafter "Martin"). Applicant respectfully traverses.

In traversing the Section 103 rejections the Applicant will first describe the deficiencies of the individual cited references and will then describe the deficiencies of the various combinations of the cited references.

Cox:

Cox is directed to a prosthesis having diamond shaped elements 73 attached to a strip of liner material 75 by being stitched with a sewing machine to form a ribbon. (Cox, column 12, lines 19-24). The ribbon may then be wound over a mandrel to form the prosthesis. (*Id.*; Fig. 5E.). The diamond shaped elements 73 are formed from at least two wires that are diagonally disposed in a zig-zag manner across the width of the liner material 75. (See, Cox, Fig. 5E). Further, the liner material is described as a woven material made from polyester or PTFE yarns. (Cox, column 12, lines 7-11). Thus, Cox describes a plurality diamond shaped elements being sewn onto a strip of woven material.

Thus, Cox fails to teach or suggest a planar assembly or strip comprising non-textile graft material as described in independent claims 1, 8 and 17.

Cox further describes the diamond shaped elements 73 as having apices 69. (Cox. column 12, lines 32-36). The apices 69 are depicted in FIG. 5E as being proximal to the edges of the strip of liner material 75. As Cox only describes the diamond shaped elements as having apices 69 at the edges of the strip 75 and does not describe apices as being at internal locations, such as the middle portion of the strip, the diamond shaped elements are formed by overlaying one wire in a zig-zag arrangement with another wire in a similar but offsetting zig-zag arrangement. Thus, the diamond shaped elements of Cox have overlaying wire portions along the middle longitudinal axis of its woven strip.

Because Cox has overlaying stent wires, the resulting structure has a significant third dimension where one wire must overlap another stent wire by at least one wire diameter. Thus,

Cox fails to teach or suggest a planar stent arrangement as defined by the present application, including the planar stent wire of claim 1, the planar stent material of claim 8, and the planar stent of claim 17.

Moreover, in other embodiments, Cox fails to teach its particular stent-grafts may be formed by helically winding planar stent-graft assemblies or are made from non-woven liners. Where Cox is silent on the particular construction details of its liner or graft materials, i.e., not specifically describing the graft yarns as being woven, Cox teaches that its stent-grafts are formed from cylindrical grafts with cylindrical reinforcing elements being axially attached thereon. (See e.g., Cox, column 13, lines 6-26). Therefore, in its other embodiments Cox not only fails to teach or suggest the present invention, but teaches away from the present invention.

Shannon:

The examiner cites Shannon for its teachings that a stent component may be disposed between two PTFE graft components.

Shannon, however, teaches that its tubular liner 12 must be first placed on a tubular mandrel 50, a tubular stent 14 is then disposed over the liner 12, and then the outer cover is disposed over the stent 14 by helically wrapping a tape 17 over the stent. (Shannon, column 10, line 50, to column 11, lines 13; and Figs. 4b-4f). The liner 12 is described as being formed by extruding PTFE through a tubular extrusion die. (Shannon, column 7, lines 32-35). The tape 17 is described as being formed by extruding PTFE through a film extrusion die. (Shannon, column 8, lines 13-17). Further, the stent is a braided stent having overlapping stent wires. (See e.g., Figs. 2 and 4c).

Thus, Shannon teaches a PTFE stent-graft is formed from an extruded tubular PTFE graft and a tubular stent, both of which are disposed over a tubular mandrel, followed by

helically wrapping an extruded PTFE tape. Such teachings, however, are in direct contrast to the claimed recitations of the present invention. Further, Shannon fails to teach or suggest a planar stent structure as claimed because of the overlapping wires of its braided stent.

Brauker:

The examiner cites Brauker for its teachings that a stent component may be disposed between two PTFE graft components.

While not admitting that Brauker is prior art to the present invention, nevertheless Brauker also fails to teach or suggest the present invention. Brauker forms its graft components by wrapping ePTFE graft material onto a mandrel (Brauker, column 9, line 66, to column 10, line 1; and column 10, lines 59-66) or by extruding tubular ePTFE onto a mandrel (Brauker, column 13, lines 13-47). Thus, Brauker forms a tubular ePTFE graft. A stent 80 is shown as having an inner liner of such tubular-formed graft, an outer cover of such tubular-formed graft, or both. Further, the stent is a braided stent having overlapping stent wires. (See e.g., Fig. 8B)

Brauker, therefore, fails to teach or suggest the formation of a planar strip of stent-graft material as set forth in the present invention. Further, Brauker fails to teach or suggest a planar stent structure as claimed because of the overlapping wires of its braided stent.

Pinchuk:

The examiner cites Pinchuk for its teachings that a graft component may be non-woven.

Pinchuk, however, forms the graft member extruding a polymer solution into fibers from a spinnerete onto a rotating mandrel to form a non-woven graft. (Pinchuk, column 5, lines 48-54). To provide a stent-graft with an exterior liner of non-woven material, Pinchuk teaches that the stent member 14 is placed directly over a mandrel and the graft member is formed by being spun thereover. (Pinchuk, column 5, lines 53-56). To provide a stent-graft with an interior liner of non-woven material, Pinchuk teaches that graft member is formed by

being spun over a mandrel and that the stent member 14 is then placed directly over graft and over the mandrel. (Pinchuk, column 5, lines 56-60). Thus, the member 14, which is shown as an undulating stent in Fig. 1, is helically wound over the underlying graft.

Pinchuk does mention the graft material may be non-spun. (Pinchuk, column 5, lines 62-65). Such non-spun grafts, however, are also prepared as tubular objects in direct contrast to the planar-stent-graft assemblies of the present invention. (See e.g., Pinchuk, column 8, lines 20-56).

Thus, Pinchuk forms a tubular stent graft by forming tubular graft components over a mandrel or over a tubular stent disposed over the mandrel.

Pinchuk, therefore, fails to teach or suggest the formation of a planar strip of stent-graft material as set forth in the present invention.

Fogarty:

The examiner cites Fogarty for its teachings that a graft component may be non-woven.

Fogarty, however, teaches the formation of a tubular stent from the cutting or etching of a hollow tubular member. (Fogarty, column 8, lines 7-26). The resultant stents are tubular slotted or mesh stents. (See e.g., Figs. 7-10). Fogarty also teaches that a polymeric, non-woven liner is then attached to the tubular stent frame. (Fogarty, column 9, lines 60-64).

Thus, Fogarty forms a tubular stent and provides a graft component over the tubular stent.

Fogarty, therefore, fails to teach or suggest the formation of a planar strip of stent-graft material as set forth in the present invention.

Dereume:

The examiner cites Dereume for its teachings that a graft component may be non-woven.

Dereume forms a non-woven graft component by an electrostatic spinning process. (Dereume, column 4, lines 25-27). A liner 24 is formed directly on a rotating mandrel. (Dereume, column 4, lines 45-46; column 8, lines 3-8). A tubular stent 22 is placed over the liner 24 while the liner 24 is still disposed over the mandrel. (Dereume, column 4, lines 47-49). Tubular stents include a braided stent, an undulating stent or a mesh stent. (See, Fig. 1, Fig. 3 and Fig. 5).

Thus, Dereume forms a tubular stent graft by forming tubular graft components over a mandrel or over a stent disposed on the mandrel.

Dereume, however, fails to teach or suggest the formation of a planar strip of stent-graft material as set forth in the present invention.

Martin:

The examiner cites Martin for its teachings that a stent may be made from nitinol and may have an undulated configuration.

Martin teaches that an undulating stent wire is to be helically wound around a mandrel to form its tubular stent. (Martin, column 13, lines 9-12). Graft material is also placed over a mandrel to form an inner tubular liner. (Martin, column 14, lines 4-6). The tubular stent removed from its mandrel and is then positioned over the inner liner, which is disposed over its mandrel, to form a stent-graft. (Martin, column 14, lines 8-10). A flat ribbon PTFE is then wrapped around the exterior surface of the stent. (Martin, column 14, lines 13-17).

Thus, Martin forms its prosthesis by individually placing different components of the prosthesis over a mandrel.

Martin, however, fails to teach or suggest the formation of a planar strip of stent-graft material as set forth in the present invention.

Applicable Law

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, it is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the express teachings of Cox, Shannon, Brauker, Pinchuk, Fogarty, Dereume and Martin, which would lead one away from the methods of the present invention, may not be ignored during examination.

Moreover, it is well established that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness and any attempt at hindsight reconstruction using Appellants' disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Independent Claims 1, 8 and 17 Are Patentably Distinct Over Cox, Shannon, Brauker, Pinchuk, Fogarty and Dereume

As discussed above, Cox is directed to a woven graft strip having overlaying stent wires sewn in a diamond or zigzag pattern. Cox fails to teach or suggest forming a planar assembly strip by, *inter alia*, attaching a planar stent or stent wire onto planar graft material because as used in the present application the use of the term planar refers to a structure that can be substantially defined by vectors in only two dimensions and not defined by a vector to any large extent in a third dimension, for example overlapping.

Further, Cox fails to teach or suggest forming a planar assembly strip by, *inter alia*, forming the assembly strip comprising non-textile graft material. The Action acknowledges

that Cox fails to teach or suggest forming a planar assembly strip by, *inter alia*, forming the assembly strip comprising a non-textile graft material, as the Action cites the secondary references for non-textile graft materials. The secondary references, however, all require that stent-grafts having non-textile graft portions be formed by methods in direct contrast to the methods of the present invention, i.e. teach away from the present invention. For example, Shannon teaches that a tubular liner must be first placed on a tubular mandrel , a tubular stent is then disposed over the liner, and then the outer cover is disposed over the stent by helically wrapping a tape over the stent (Shannon, column 10, line 50, to column 11, lines 13; and Figs. 4b-4f); Brauker forms its graft by wrapping graft material onto a mandrel or by extruding a tubular graft onto a mandrel (Brauker, column 9, line 66, to column 10, line 1; column 10, lines 59-66; column 13, lines 13-47); Pinchuk forms a tubular a tubular graft by spinning fibers onto a rotating mandrel to form a non-woven graft and separately places a tubular stent over a mandrel to form its stent-graft (Pinchuk, column 5, lines 48-56); Fogarty forms a tubular stent from the cutting or etching of a hollow tubular member to which a liner is then attached to the tubular stent (Fogarty, column 8, lines 7-26; Fogarty, column 9, lines 60-64); and Dereume forms its graft directly on a rotating mandrel by an electrostatic spinning process and the stent is placed over the graft while the graft is still disposed over the mandrel (Dereume, column 4, lines 25-27; column 4, lines 45-46; column 8, lines 3-8; column 4, lines 47-49).

Such express teachings of Shannon, Brauker, Pinchuk, Fogarty and Dereume, which would lead one away from the methods of the present invention, may not be ignored during examination. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, the Examiner is prohibited against ignoring such contradictions while only picking portions that support the alleged rejections. *Id.*

Thus, the only teaching of forming a planar stent-graft assembly comprising a non-textile planar graft strip and a planar stent is Applicant's own specification, and any hindsight

reconstruction of the cited references to present a *prima facie* case of obviousness is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, Cox, Shannon, Brauker, Pinchuk, Fogarty and Dereume, individually or in any combination, fail to teach or suggest the present invention as presently defined in independent claims 1, 8 and 17. Reconsideration and withdrawal of the rejections of claims 1-9, 11-24 and 26 are therefore respectfully requested.

Claims 8 and 25 Are Patentably Distinct Over Cox, Shannon, Brauker, Pinchuk, Fogarty, Dereume and Martin

The action cited Martin for its teachings of an elongate undulating stent wire and of nitinol being used as a stent material.

While Martin discloses an elongate undulating stent, none of the stent-grafts disclosed therein are produced in accordance with claimed recitations of the subject application. For example, Martin forms its stent-graft by placing graft material over a mandrel; winding a stent wire around a mandrel to form its tubular stent, and wrapping a flat PTFE ribbon around the exterior surface of the stent. (Martin, column 13, lines 9-12; column 14, lines 4-17).

Additionally, the teachings of the other cited references, such as Pinchuk and Dereume, which also disclose an elongate undulating wire stent, are also contrary to the claims of the present invention. For example, Pinchuk forms a tubular a tubular graft by extrusion onto a rotating mandrel to form a non-woven graft and separately places a tubular stent over a mandrel to form its stent-graft (Pinchuk, column 5, lines 48-56), and Dereume forms its graft directly on a rotating mandrel by an electrostatic spinning process and the stent is placed over the graft while the graft is still disposed over the mandrel (Dereume, column 4, lines 25-27; column 4, lines 45-46; column 8, lines 3-8; column 4, lines 47-49).

Further, as discussed above, Shannon, Brauker and Fogarty and Dereume, which do not disclose an undulating stent wire, also require stent-grafts be formed by methods in direct contrast to the method of the present invention of forming a planar assembly strip, i.e., teach away from the present invention.

The express teachings of Shannon, Brauker, Pinchuk, Fogarty, Dereume and Martin, which would lead one away from the methods of the present invention, may not be ignored during examination. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, the Examiner is prohibited against ignoring such contradictions while only picking portions that support the alleged rejections. *Id.*

Thus, the only teaching of forming a stent-graft assembly comprising a non-textile planar graft strip and a planar stent is Applicant's own specification, and any hindsight reconstruction of the cited references to present a *prima facie* case of obviousness is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, Cox, Shannon, Brauker, Pinchuk, Fogarty, Dereume and Martin, individually or in any combination, fail to teach or suggest the present invention as presently defined in claims 10 and 25.

Therefore, reconsideration and withdrawal of the rejection of claims 10 and 25 are respectfully requested.

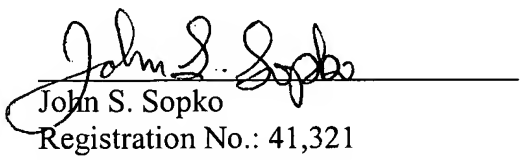
Summary

Therefore, Applicant respectfully submits that independent claims 1, 8 and 17, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461.

Respectfully submitted,



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